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TOPICORT® Ointment (desoximetasone) 0.25%

Brief Summary—Consult Package Insert for Full Prescribing Information

DESCRIPTION: Each gram of Topicort® Ointment (desoximetasone) 0.25% contains 2.5 mg of desoximetasone in a base of white petrolatum, propylene glycol, sorbitan sesquioleate, beeswax, fatty alcohol citrate, fatty acid pentaerythritol ester, citric acid, aluminum stearate and butylated hydroxyanisole.

INDICATIONS: For relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS: History of hypersensitivity to any component of the preparation.

PRECAUTIONS: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Conditions which augment systemic absorption include application of the more potent steroids, use over large surface areas, prolonged use, and addition of occlusive dressings. When these conditions exist, evaluate patients periodically for evidence of HPA axis suppression, using urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, attempt to withdraw the drug, reduce the frequency of application, or substitute a less potent steroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity.

If irritation develops, discontinue topical corticosteroids and institute appropriate therapy. In the presence of dermatological infections, institute use of an appropriate antifungal or antibacterial agent. If favorable response does not occur promptly, discontinue the corticosteroid until infection has been adequately controlled. Avoid contact with the eyes.

Long-term animal studies have not been performed to evaluate the carcinogenic potential or effect on fertility of topical corticosteroids. Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. They should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Advise parents not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings. Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with growth and development of children. Safety and effectiveness in children below the age of 10 have not been established.

ADVERSE REACTIONS: The following local adverse reactions, listed in approximate decreasing order of occurrence, are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, periorificial dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria. In controlled clinical studies, the incidence of adverse reactions was low (0.3%) and consisted of development of comedones at the site of application.

HOW SUPPLIED: Topicort® Ointment (desoximetasone) 0.25% is supplied in 15- and 60-gram tubes.

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